



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,060	11/08/1999	James T Kealey	014/002C	6093
53456 7590 07/16/2008 GERON CORPORATION Attn. David J. Earp 230 CONSTITUTION DRIVE MENLO PARK, CA 94025				
EXAMINER				
GIBBS, TERRA C				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
07/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/436,060

Applicant(s)

KEALEY ET AL.

Examiner

TERRA C. GIBBS

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 35-37 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed March 17, 2008.

Claims 40 and 41 have been canceled. New claim 45 is acknowledged. Claim 44 has been amended.

Claims 35-39 and 42-45 are pending in the instant application.

Claims 35-39 and 42-45 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102/103

In the previous Office Action mailed October 17, 2007, claims 35, 36, 40, 41, and 44 were rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Villeponteau et al. [U.S. Patent No. 5,776,679]. **This rejection is moot** against claims 40 and 41 in view of Applicant's Amendment filed March 17, 2008 to cancel these claims. **This rejection is withdrawn** against claims 35, 36, and 44 in view of Applicant's Amendment filed March 17, 2008. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 44 to remove recitation of "nucleotides 137-196".

In the previous Office Action mailed October 17, 2007, claims 37 and 44 were rejected under 35 U.S.C. 103(a) as being anticipated by Villeponteau et al. [U.S. Patent

Art Unit: 1635

No. 5,776,679] in view of Nakamaye et al. (Nucleic Acids Research, 1988 Vol. 16:9947-9959). **This rejection is withdrawn** in view of Applicant's Amendment filed March 17, 2008. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 44 to remove recitation of "nucleotides 137-196".

In the previous Office Action, it was noted that claims 42 and 43 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, after careful reconsideration, a new ground(s) of rejection is made of record as detailed below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35-37 and 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,968,506 ('506).

Claim 44 is drawn to a pharmaceutical composition consisting of a polynucleotide and a pharmaceutically acceptable carrier, wherein the polynucleotide (a) has a sequence of at least 7 nucleotides that specifically hybridizes to the first nucleotide sequence within an accessible region of the RNA component of a human telomerase (hTR), wherein the accessible region is selected from the group consisting of nucleotides 290-317 and nucleotide 350-380 of hTR (SEQ ID NO:16), (b) does not hybridize to a second nucleotide sequence within the template region of the hTR, said template region being nucleotides 46-55 of SEQ ID NO:16, and (c) is effective to inhibit the synthesis of telomeric DNA by telomerase. Claims 36, 37, and 43-45 are dependent on claim 44 and include all the limitations of claim 44 with the further limitations wherein said polynucleotide has a sequence of about 10 to about 50 or about 15 to about 35 nucleotides that specifically hybridizes to the first nucleic acid sequence; wherein said polynucleotide comprises 2'-O-methyl ribonucleotides; and wherein said polynucleotide comprises at least 7 nucleotides that specifically hybridizes to the first nucleotide

sequence within an accessible region of the RNA component of a human telomerase (hTR), wherein the accessible region of the RNA component of a human telomerase (hTR), said accessible region being nucleotides 350-380 of SEQ ID NO:16.

'506 discloses (Oligo 14ab) (SEQ ID NO:7), with the following sequence:

5'-cgttcctctt cctgcgcct-3'

It is noted that Oligo 14ab will specifically hybridize with at least nucleotides 361-380 of hTR (SEQ ID NO:16) since this oligo is 100% complementary to nucleotides 361-380 of SEQ ID NO:16. '506 specifically discloses that, "Oligo 14ab hybridizes to a region of hTR that is accessible in the holoenzyme". '506 also discloses that Oligo comprises biotinylated 2'-O-methyl ribonucleotides. '506 discloses that Oligo14ab is used in affinity chromatography and applied to a gel column equilibrated in buffer, which constitutes a pharmaceutically acceptable carrier.

Therefore, '506 anticipates claims 35-37 and 43-45.

Claims 35-37 and 42-45 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,846,723 ('723). Claims 35-37, 44, and 45 are as described above. Claim 42 is dependent on claim 44 and include all the limitations of claim 44 with the further limitation wherein said polynucleotide comprises at least 7 nucleotides that specifically hybridizes to the first nucleotide sequence within an accessible region of the RNA component of a human telomerase (hTR), wherein the accessible region of the RNA component of a human telomerase (hTR), said accessible region being nucleotides 290-319 of SEQ ID NO:16.

'723 discloses (Oligo 16) SEQ ID NO:5 with the following sequence:

5'-CTGACAGAGCCCCAACTCTTCGCGGTGGCAG-3'

It is noted that Oligo 16 corresponds to nucleotides 290-319 of hTR, thus Oligo 16 will specifically hybridize to nucleotides 290-319 of SEQ ID NO:16 of Applicant's invention. '723 discloses that oligonucleotides of their invention comprise pharmaceutical compositions, pharmaceutically acceptable carriers, and 2'-O-methyl RNA. It should also be noted that '723 also discloses Oligo 14ab as disclosed in '506 above.

Therefore, '723 anticipates claims 35-37 and 42-45.

Allowable Subject Matter

Claims 38 and 39 are allowable. Claims 38 and 39 are considered to be free of the prior art since the prior art does not teach or fairly suggest a polynucleotide consisting of a sequence selected from the group consisting of SEQ ID NOs: 2-14 or pharmaceutical compositions therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

July 15, 2008
/Terra Cotta Gibbs/